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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,831	12/30/2003	Richard L. Boyd	NOR-016CP2 and 286336.155	2793

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,831	BOYD, RICHARD L.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-82 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-82 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-82 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction

I. Claims 1-78, drawn to a method for genetically altering a subject or a patient or a method for preventing infection of a patient by HIV or a method of treating HIV infection in a patient comprising at least the step of administering genetically modified cells to the patient, classified in class 424, subclass 93.21.

II. Claims 79-80, drawn to a method for delivering a sex steroid analog to a patient, classified in class 424, subclass 198.1.

III. Claim 81, drawn to a method for enhancing transplantation of donor hematopoietic stem cells into the thymus of a recipient patient, classified in class 424, subclass 93.1.

IV. Claim 82, drawn to a method for increasing virus-specific peripheral T cell responsiveness of a patient with an at least partially atrophied thymus comprising reactivating the thymus of the patient and exposing the patient to a virus, classified at least in class 424, subclass 93.1.

The inventions are distinct because of the following reasons:

The methods of Groups I-IV are drawn to distinct methods having different starting materials, different method steps and different desired end-results, and therefore they would require different technical considerations for achieving these different desired end-results. For example, Group I is drawn specifically to a method for genetically altering a subject or a patient or a method for preventing infection of a patient by HIV or a method of treating HIV infection in a patient comprising at least the step of administering genetically modified cells to the patient; Group II is directed specifically to a method for delivering a sex steroid analog to a patient without requiring any cell transplantation or virus exposure; Group III is drawn to a method for enhancing transplantation of donor hematopoietic stem cells into the thymus of a recipient patient without the requirement of any genetically modified cell transplantation or virus exposure; and Group IV is directed specifically to a method for increasing virus-specific peripheral T cell responsiveness of a patient with at least partially atrophied thymus containing the step of exposing the patient to a virus, which is not required in any of the methods of Groups I-III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements in both patent and non-patent literature searches due to the distinctness of the inventions as set forth above, it would be unduly burdensome for the examiner **to search and/or consider the patentability of all the inventions** in a single application, restriction for examination purpose as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species Restriction

A. Should Applicants elect the invention of Group I, this application contains claims directed to the following patentably distinct species of disruption of sex-steroid-mediated signaling to the thymus to reactivate the thymus of the claimed invention:

1. surgical castration; 2. chemical castration; and 3. administration of one or more pharmaceuticals.

The species are independent or distinct because a surgical castration, a chemical castration, and the administration of one or more pharmaceuticals are distinct processes utilizing different techniques and materials.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 19, 27, 41, 65 and 72 are generic.

Additionally, should Applicants elect the species 3 above, this application contains claims directed to the following patentably distinct species of a pharmaceutical of the claimed invention:

a. LHRH agonists; b. LHRH antagonists; c. anti-LHRH vaccines; d. anti-androgens; e. anti-estrogens; f. SERMs; g. SARMs; h. SPRMs; i. ERDs; j. aromatase inhibitors; k. anti-progestogens; l. Dioxalan derivatives; or m. a specific combination of species a-l.

The species are independent or distinct because each pharmaceutical is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 17, 19, 25, 27, 41, 49-50, 65 and 72 are generic.

(i) Additionally, should Applicants elect the a species containing LHRH agonists, this application contains claims directed to the following patentably distinct species of LHRH agonists of the claimed invention:

A specific named LHRH agonist or a specific combination of LHRH agonists recited in the Markush group of claim 51.

The species are independent or distinct because each recited LHRH agonist is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

finally held to be allowable. Currently, at least claims 1, 17-19, 25-27, 41, 49-51, 65 and 72 are generic.

(ii) Additionally, should Applicants elect the a species containing LHRH antagonists, this application contains claims directed to the following patentably distinct species of LHRH antagonists of the claimed invention:

A specific named LHRH antagonist or a specific combination of LHRH antagonists recited in the Markush group of claim 52.

The species are independent or distinct because each recited LHRH antagonist is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 17, 19, 25, 27, 41, 49-50, 52, 65 and 72 are generic.

This application contains claims directed to the following patentably distinct species of genetically modified cells to the patient of the claimed invention:

A specific named genetically modifying cells or a specific combination of genetically modifying cells recited in the Markush group of claim 1.

The species are independent or distinct because each recited genetically modifying cell type is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1,19, 27, 65 and 72 are generic.

This application contains claims directed to the following patentably distinct species of conditions in the claimed invention:

(a) T cell functional disorder; (b) HIV infection; (c) T cell leukemia virus infection; or (e) a single specifically named virus selected from a Markush group of claim 54.

The species are independent or distinct because each condition is caused by a distinct agent that has different structure and properties one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 8-9, 27 and 53-54 are generic.

This application contains claims directed to the following patentably distinct species of a polynucleotide expressible in genetically modifying cells in the claimed invention:

(a) nef transcription factor gene; (b) a gene that codes for a ribozyme that cuts HIV tat; (c) a gene that codes for a ribozyme that cuts rev gene; (d) a ribozyme that cuts HIV tat and rev genes; (e) RevM10; (f) HIV-1 rev-responsibe element; (g) CXCR4; and (h) PolyTAR.

The species are independent or distinct because each polynucletoide is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1, 8-9, 12-13, 19-21, 27, 55-58, 65 and 72 are generic.

This application contains claims directed to the following patentably distinct cytokine species, growth factor species or combination of cytokine and growth factor species:

A single specific named cytokine species or a single specific named growth factor or a single specific combination a cytokine and a growth factor recited in claims 61-63.

The species are independent or distinct because each recited cytokine, growth factor is structurally and biochemically distinct one from the others; and therefore each specific combination of a cytokine and a growth factor is also distinct from other combinations.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 27 and 61 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Dave Nguyen, may be reached at (571) 272-0731.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

QUANG NGUYEN, PH.D
PATENT EXAMINER